Office of Generic Drugs

Reassignment of Bioequivalence Reviews

CONTENTS

PURPOSE

- This MAPP explains the policy and process to follow when assigning the review of a submission from one reviewer to another in the Division of Bioequivalence (DBE) to prevent a delay in completing that review.

BACKGROUND

- It is DBE policy to assign abbreviated new drug applications (ANDA) and related documents (generic drug submissions) to bioequivalence reviewers according to the Office of Generic Drugs' random assignment policy for generic drug submissions.

- Situations may arise when a reviewer is unable to review an already assigned submission in a timely manner. This may be due to the reviewer's unexpected absence or planned extended absence. The reviewer also could be unable to continue a review because of the need to work on a top priority special project assigned by the division or office management. In such instances, the reassignment procedures outlined in this MAPP should be followed.

REFERENCES

- Office of Generic Drugs Policy and Procedure Guide #39-94 - ARandom Assignment of Original Applications to Chemistry Reviewers.@
- Office of Generic Drugs Policy and Procedure Guide #42-95 – "Random Assignment of Original Applications and Related Document to Bioequivalence Reviewers."

POLICY

If at any time a reviewer is unable to initiate or complete the review of a bioequivalence application or amendment or other review assignment within a specified time period, it should be reassigned to the next available reviewer.

The need for reassignment will be determined by the status of the submission and the time the reviewer is unavailable (see below). If the reviewer was able to complete a draft review, it is left to the discretion of the team leader whether to complete the review instead of reassigning it. If a team leader completes the review, the secondary review should be done by another team leader or the deputy division director.

Generic Drug Submission Status	Time Reviewer Unavailable
Original Application	2 Weeks (or more)
Major Amendment	2 Weeks (or more)
Minor Amendment	1 Week
FAX Amendment	1 Week
Telephone Amendment	1 Week

A reassignment determination and rationale must be documented in a memorandum to the file of the reassigned application. See Attachment A.

RESPONSIBILITIES

Division Director

- Concurs in reassignments, when appropriate, by signing the Application Reassignment Authorization Form (See Attachment A).

Team Leader

- Monitors work queues and reviewer absences to determine if reassignment is appropriate. Alerts Division Director to the need for reassignment of review work.
- Prepares the Application Reassignment Authorization Form including stating the reason for the reassignment and obtains the Division Director's concurrence and signature on the reassignment form.
- Forwards signed memorandum to the DBE Project Manager.
- Provides secondary review for work reassigned to any member of his/her team.

DBE Project Managers

- Maintains the DBE review queue and related files.
- Changes the computer management information system (OGD MIS) to reflect reassignments and forwards the signed authorization form to the document room for filing.
- Places a copy of the form in DBE's Reassignment Authorization File.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT A

APPLICATION REASSIGNMENT AUTHORIZATION FORM
OFFICE OF GENERIC DRUGS

ANDA #	DRUG	FIRM

1. REASSIGN FROM:_____

   DATE OF ORIGINAL ASSIGNMENT:_____

2. DATE OF REASSIGNMENT:_____

   REASON FOR REASSIGNMENT:_____

   _____

   _____

   _____

_____ DATE:_____
TEAM LEADER (SIGNATURE)

_____ CONCUR:_____ NOT CONCUR:_____
BIOEQUIVALENCE DIVISION
DIRECTOR (SIGNATURE) DATE:_____

A COPY OF THIS FORM SHOULD BE PLACED IN EACH APPLICATION AND IN THE DIVISION FILE